Ameridose, LLC-
Complaint file-(PHA-2010-0107) –
Allegation of Complaint: manufacture and distribution of non-approved FDA products.

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD
SECRETARY

JOHN AUERBACH
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy
239 Causeway Street, Suite 500, 5th Floor
Boston, MA 02114
(800) 414-0168
http://www.mass.gov/reg/boards/pharmacy

June 6, 2011

James N. Czaban, Esq.
Wiley Rein, LLP
1776 K Street NW
Washington, DC 20006

RE: Complaint Docket Nos. PHA20100107 and PHA20100108

Dear Atty. Czaban:

The Board of Registration in Pharmacy (Board) has voted to resolve the above-referenced complaints by issuing a Dismissal Letter (enclosed) to Ameridose, LLC pharmacies located in Westborough, Massachusetts.

Thank you for bringing this matter to the attention of the Board.

Very truly yours,

Stanley B. Walczyk, R.Ph, President
Board of Registration in Pharmacy

Encls.

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy
239 Causeway Street, Suite 500, 5th Floor
Boston, MA 02114
(800) 414-0168
http://www.mass.gov/reg/boards/pharmacy

In the Matter of:)
Ameridose, LLC)
201 Flanders Road)
Westborough, MA 01581)
Pharmacy Registration No. DS89750)

Docket No. PHA20100107

DISMISSAL LETTER

The Board of Registration in Pharmacy ("Board") investigated a complaint alleging that that on or about June 30, 2010, Ameridose, LLC, a pharmacy licensed by the Board (No. DS89750) located at 201 Flanders Road, Westborough, Massachusetts (formerly 50 Fountain Street, Framingham, Massachusetts) (No. DS3467) ("Pharmacy"), was engaged in the manufacture and distribution of two products that were not approved by the U.S. Food and Drug Administration; specifically, pre-mixed nicardipine injection (Nicardipine (2.5mg/ml) in 10ml glass ampoules for dilution in 240 ml of intravenous fluid) and pre-mixed Cardene ® I.V. Injection (Cardene ® I.V. 20mg or 40mg (0.1mg/ml or 0.2 mg/ml)) in 200ml Galaxy® bags.

On March 8, 2011, after review of the complaint investigative report and other information related to the complaint, including additional information provided by the complainant, the Board voted to **Dismiss the complaint without prejudice.**

The complaint and related documents are public records which will remain on file with the Board.

PER ORDER OF THE BOARD

Stanley B. Walczyk, R.Ph, President
Date: June 6, 2011

Board Dec. No.2566
cc: Complainant

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 200
Boston, MA 02114
Office of Public Protection
(617) 973-0865 Fax (617) 973-0985 TTY (617)-973-0895

C-184

INSPECTION REPORT

Date of Inspection 07/08/10 Reg. No. RS89641 Expiration Date 12/31/11

Purpose of Inspection New Location ____ Relocation ____ Compliance ✓

Docket No. OR Staff Assignment No. PHA-2010-0107

Corporation Name AmeriDose

Pharmacy DBA Name AmeriDose Store No. ____

Address 205 Flanders Road, Westborough MA

Telephone No. 508-820-0606 Fax No. 508-475-0421

Manager of Record [redacted] Reg. No. [redacted]

Pharmacy DEA Registration No. and Expiration Date [redacted]

Pharmacy Hours Daily 6AM - 8PM Saturday 6AM - 6PM Sunday closed

Practice Setting Community Chain ____ With Drive-thru Window ____
Community Independent ____ Specialty ✓ Long Term Care ____

Daily Pharmacy Volume N/A Less than 100 ____ 100 to 500 ____ Above 500 ____

Staff Pharmacists (Names and Registration Numbers)
See attached

also manufacturer license:
RA0378960
exp 6/30/11

Pharmacy Interns (Names and Registration Numbers)

Pharmacy Technicians (Names, Registration Numbers and Certification Status)
See attached

Other Pharmacy Support Staff and Trainees (Names and positions)

AMERI DOSE

205 Flanders Road, Westborough, MA 01581
Tel: 508-656-2633, Fax: 508-872-0044

LIST OF ALL REGISTERED PHARMACISTS

NAME	TITLE	ADDRESS	LICENSE #
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. 12-31-10
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted]

NAME	TITLE	ADDRESS	LICENSE #
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Mgr of Record	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]
[redacted]	Staff Pharmacist	[redacted]	[redacted] Exp. [redacted]

AMERI-DOSE

205 Flanders Road, Westborough, MA 01581
Tel: 508-656-2633, Fax: 508-872-0044

LIST OF ALL REGISTERED PHARMACY TECHNICIANS

NAME	TITLE	ADDRESS	LICENSE #
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]		[redacted]	[redacted]

NAME	TITLE	ADDRESS	LICENSE #
		[redacted]	[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted]

NAME	TITLE	ADDRESS	LICENSE #
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp. [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp. [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Ex[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]		[redacted]	[redacted]

NAME	TITLE	ADDRESS	LICENSE #
[redacted]	[redacted]	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted]

NAME	TITLE	ADDRESS	LICENSE #
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Ex[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Ex[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Ex[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Ex[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Ex[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp[redacted]
[redacted]	Registered Technician	[redacted]	[redacted] Exp [redacted]
[redacted]		[redacted]	[redacted]

NAME	TITLE	ADDRESS	LICENSE #
		[redacted]	[redacted]

SECURITY - 247 CMR 6.02 and CFR 1301.75(b)	YES	NO
ADEQUATE SECURITY SYSTEM	✓	
EVIDENCE OF SECURITY CAMERAS	✓	
SECURITY BARRIER SEPARATES PHARMACY DEPARTMENT	✓	
PROCEDURE FOR ABSENCE OF PHARMACIST	✓	
CONTROLLED SUBSTANCES ARE LOCKED IN A SECURE CABINET a list I (ephedrine)	✓	
CONTROLLED SUBSTANCES ARE DISPERSED THROUGHOUT GENERAL INVENTORY		✓
LOSS OR THEFT OF CONTROLLED SUBSTANCES (DEA FORM 106) REPORTED TO THE BOARD	✓	
SECURITY/ACCESS TO PHARMACY RESTRICTED TO AUTHORIZED PERSONNEL	✓	
COMMENTS:		

LICENSURE/REGISTRATION STATUS OF PHARMACY STAFF	YES	NO
COPIES OF PHARMACIST LICENSES ARE POSTED AND CURRENT	✓	
COPIES OF TECHNICIAN REGISTRATIONS ARE CURRENT AND AVAILABLE	✓	
PROCEDURES IN PLACE TO MAINTAIN PATIENT CONFIDENTIALITY WITH REGARD TO DISCARDED PRESCRIPTION INFORMATION (e.g. SHREDDER) SECURED SHREDDERS	✓	
COMMENTS:		

STANDARDS FOR PRESCRIPTION LABELING AND FORMAT M.G.L. c. 94C, § 21 and CMR 721.000	YES	NO
PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF Rx	✓	
"BEYOND USE" DATE IS SHOWN ON LABEL	✓	
INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED	✓	
LABEL COMPLIANT WITH INTERCHANGE	✓	
PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION	✓	
ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED	✓	
COMMENTS		

OUTDATED ITEMS/RETURN TO STOCK	YES	NO
QUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT SEGREGATED FROM CURRENT INVENTORY	✓	
COMMENTS (reliable pharmaceutical) RP Returns		

CONTROLLED SUBSTANCE RECORDS/EDT 21 CFR PART 1300 – 1308 and 247 CMR 5.00	YES	NO
PRESCRIPTION RECORDS ARE ON SITE AND READILY RETRIEVABLE FOR 2 YEARS	✓	

CONTROLLED SUBSTANCE RECORDS/EDT 21 CFR PART 1300 – 1308 and 247 CMR 5.00 (continued)	YES	NO
THE LAST BIENNIAL INVENTORY COMPLETED 12/31/09 AND SHOWS BEFORE OPENING OR AFTER CLOSING finished goods, QA lab, QA samples vault, clean room	✓	
POWER OF ATTORNEY GRANTED TO PERSONS SIGNING DEA FORM 222 AND READILY AVAILABLE	✓	
POWER OF ATTRONEY FORM FOR DEA FORM 222 GRANTED TO: Bryan O'Neill & Sophie Fasoulis	✓	
COMPLETE RETURN AND DESTRUCTION RECORDS OF CONTROLLED SUBSTANCES READILY AVAILABLE	✓	
EMERGENCY C-II PRESCRIPTION RECORDS ARE COMPLETE AND PROPERLY FILED	✓	
SCHEDULE II PRESCRIPTION DATA TRANSMITTED BY COMPUTER ON TIME (EDT)	✓	
CENTRAL RECORD KEEPING AUTHORITY FILED WITH DEA		✓
DEA ORDER FORMS FILLED OUT COMPLETELY, INCLUDING DATE AND QUANTITY RECEIVED	✓	
CII ORDER FORMS RECONCILED SATISFACTORILY	✓	
CIII-V INVOICES RECONCILED SATISFACTORILY	✓	
DAILY REPORTS ARE AVAILABLE, VERIFIED, AND SIGNED BY ALL PHARMACISTS INVOLVED	✓	
CII PERPETUAL INVENTORY RECONCILED WITHIN 10 DAYS 7/6/10, PRIOR: 6/28	✓	
COMMENTS:		

TRANSFER OF PRESCRIPTIONS - 247 CMR 9.02	YES	NO
CORRECT TRANSFER RECORDS ARE MAINTAINED AND READILY AVAILABLE	N/A	
DAILY REPORTS ARE AVAILABLE, VERIFIED AND SIGNED BY ALL PHARMACISTS INVOLVED		
PATIENT PROFILES ARE MAINTAINED		
COMMENTS only CVVH = pt specific CVVH = continuous veno-venous-hemofiltration		

EQUIPMENT and REFERENCE SOURCES - 247 CMR 6.01	YES	NO
COMPUTER SOFTWARE NAME: Extra-net (Sequel-Server / Cofusion)	✓	
TORSION BALANCE AND WEIGHTS SEALED DATE by Mettler Toledo rotation annually	✓	
COMPOUNDING LOG MAINTAINED	✓	
APPROPRIATELY SIZED SAFETY CONTAINERS AVAILABLE AND USED ROUTINELY (16 CFR 1700)	✓	
CURRENT COPY OR E-VERSION OF APPROPRIATE COMPENDIA REFERENCE AVAILABLE	✓	
CURRENT COPY OR E-VERSION OF MA BOARD OF PHARMACY REGULATIONS AVAILABLE	✓	
CURRENT COPY OR E-VERSION OF MA LIST OF INTERCHANGEABLE DRUGS AVAILABLE	✓	
COMMENTS Scales: Mettler Toledo 1900 Polaris Parkway Columbus OH 43240 1-800-Mettler		

CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM QUALITY RELATED EVENTS (QRE) - 247 CMR 15.00	YES	NO
CURRENT COPY OR E-VERSION OF CQI PROGRAM AVAILABLE	✓	
QRE RECORDS (2 YEARS) ARE MAINTAINED IN AN ORDERLY MANNER AND FILED BY DATE	✓	
PHARMACY PROVIDES PERSONNEL WITH ONGOING CQI EDUCATION AT LEAST ANNUALLY	✓	
POLICY AND PROCEDURES ON SITE RELATED TO THE HANDLING OF MEDICATION ERRORS	✓	
COMMENTS		

PATIENT COUNSELING 247 CMR 6.01 and 9.07; M.G.L. c. 94C, § 21A	YES	NO
PATIENT COUNSELING SIGNS (11" x 14") POSTED ~~(INCLUDING DRIVE THRU)~~		N/A
ADEQUATE OFFER TO COUNSEL MADE AND DOCUMENTED		N/A
DESIGNATED CONFIDENTIAL PATIENT COUNSULTATION AREA		N/A
COUNSELING AREA ASSURES PRIVACY AND CONFIDENTIALITY	✓	
PROSPECTIVE DUR ON NEW PRESCRIPTIONS CONDUCTED	when applicable limited to CVH	
COMMENTS		

SANITATION - 247 CMR 6.02 and 9.01	YES	NO
PHARMACY (INCLUDING SINK, REFRIGERATOR, COUNTING TRAYS, AND AUTOMATED DISPENDING MACHINES) KEPT CLEAN AND ORGANIZED	✓	
REFRIGERATOR MAINTAINED WITHING RANGE COMPLIANT WITH ~~STORAGE OF~~ DRUGS REQUIRING REFRIDGERATION TEMP. USP compliant	✓	
ROOM TEMPERATURE IS 59 - 77 DEGREES F.	✓	
PRESCRIPTION COUNTER IS USED ONLY FOR PREPARING PRESCRIPTIONS	✓	
PRESCRIPTION DEPARTMENT HAS SPACE ADEQUATE FOR THE SIZE AND SCOPE OF PHARMACEUTICAL SERVICES PROVIDED BY THE PHARMACY	✓	
SUFFICIENT EQUIPMENT TO COMPOUND AND DISPENSE PRESCRIPTIONS	✓	
SINK HAS HOT AND COLD RUNNING WATER	✓	
COMMENTS multiple refrigerators all refrigs have certified, calibrated thermometers & temp logs		

CENTRAL INTRAVENOUS ADMIXTURE SERVICE (CIVAS) 247 CMR 6.01(5)(c)	YES	NO
CLEAN ROOM - MINIMUM OF 72 SQUARE FEET	✓	
CLEAN ROOM ADJACENT TO PRESCRIPTION DEPARTMENT	✓	
HOODS: HORIZONTAL - mostly 65/70 VERTICAL - biological safety cabinets also penicillin room vented out	✓	
CIVAS APPROVAL LETTER FROM BOARD MAINTAINED ON PREMISES		✓

CENTRAL INTRAVENOUS ADMIXTURE SERVICE (CIVAS) 247 CMR 6.01(5)(c) continued	YES	NO
WRITTEN QUALITY ASSURANCE GUIDELINES MAINTAINED ON PREMISES	✓	
TRAINING IN STERILE PROCEDURE AVAILABLE AND CONDUCTED	✓	
ADEQUATE REFERENCE STANDARDS	✓	
ANNUAL CERTIFICATION OF LAMINAR HOOD AND CLEAN ROOM CONDUCTED	✓	
COMMENTS: Scientific Air of Ashland certifies hoods		

TECHNICIANS - 247 CMR 8.00	YES	NO
PHARMACY TECHNICIANS OPERATE WITHIN THE SCOPE OF LAW AND REGULATIONS	✓	
TECHNICIANS WEAR NAME TAGS EASILY READABLE WITH TITLE AND NAME	✓	
TECHNICIANS FOLLOW DUTIES AS SPECIFIED IN WRITTEN POLICIES AND PROCEDURES	✓	
TECHNICIANS ARE SUPERVISED BY A PHARMACIST	✓	
COMMENTS:		

VACCINATION/CPR - 105 CMR 700.004	YES	NO
PHARMACIST ADMINISTERING VACCINES TO PERSONS 18 YEARS OF AGE OR OLDER		
CURRENT CPR CARD		
ADMINISTRATION IS CONDUCTED PURSUANT TO THE ORDER OF A PRACITIONER N/A		
DOCUMENTATION OF ACCREDITED TRAINING		
COMMENTS:		

MANAGER OF RECORD (MOR) - 247 CMR 6.07	YES	NO
MOR CAN DEMONSTRATE IMPLEMENTATION OF A CQI PROGRAM	✓	
MOR HAS COPIES OF CONFIDENTIALITY STATEMENTS FROM EACH EMPLOYEE	✓	
MOR IS RESPONSIBLE FOR ESTABLISHING AND MONITORING POLICIES AND PROCEDURES:	✓	
(a) STAFF TRAINING ONGOING	✓	
(b) TECHNICIAN MANUAL ON PREMISES	✓	
(c) RATIO PHARMACIST TO SUPPORT PERSONNEL 1 : 2.85	✓	
NO. ON STAFF: 67	✓	
PHARMACISTS 20 PHARMACY INTERNS 0		
REGISTERED TECHS 50 CERTIFIED TECHS 7 TECHS IN TRAINING 0		
COMMENTS: See attached roster of staff on duty at time of inspection		

AMERIDOSE
Sterile Admixing Services

50 Fountain Street
Framingham, MA 01702
Toll Free: 888.820.0622
Fax: 508.872.0044
www.ameridose.com

July 12, 2010

Cheryl Lathum
Board of Registration in Pharmacy
239 Causeway Street
Suite 200, 2nd Floor
Boston, MA 02114

RE: Tech/RPH Ratio

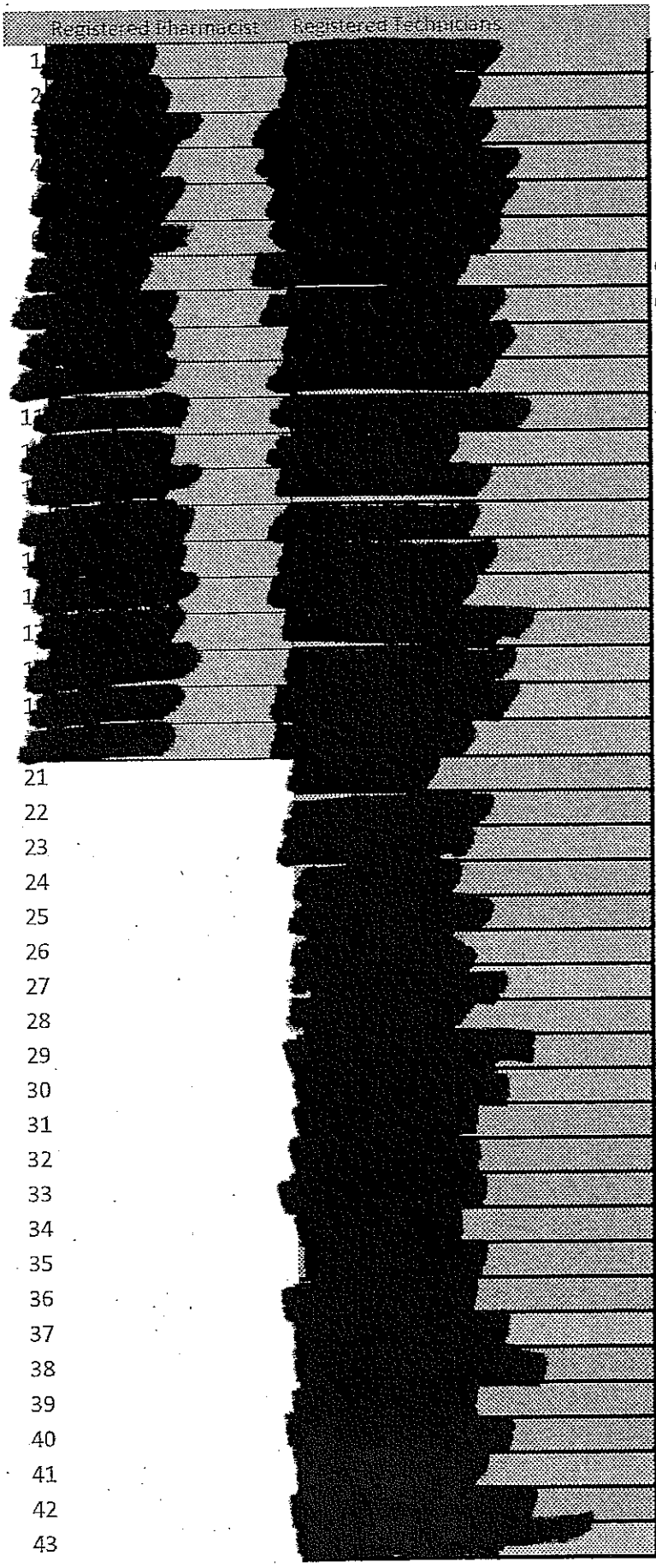
Dear Ms. Lathum:

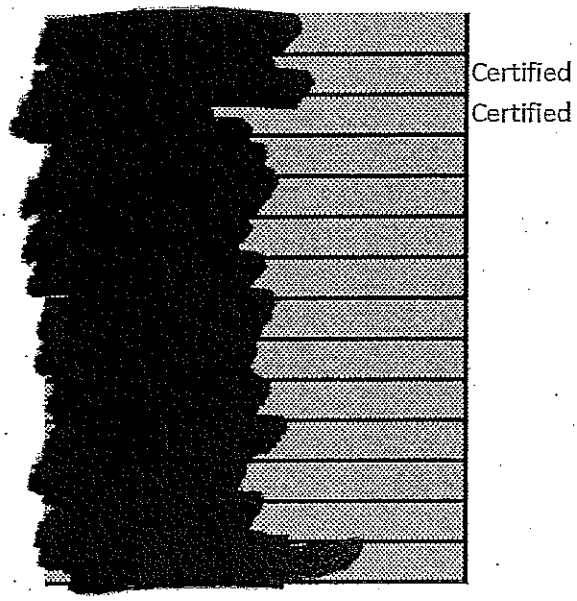
Per your request, please find attached the Tech/RPh ratio, including the names of the Pharmacists & Pharmacy Technicians who work for Ameridose, LLC.

Should you have any questions or require more information, feel free to contact me at (508) 816-7250.

Sincerely,

Bryan M. O'Neill
Director of Pharmacy


Registered Pharmacist
Registered Technicians
Certified
Certified
Certified
Certified
Certified


Certified
Certified

WHOLESALE DISTRIBUTOR INFORMATION

NAME(S) OF SUPPLIERS: Hospira + McKesson

GENERAL	YES	NO
PHARMACY GRANTED ANY WAIVERS BY THE BOARD OR DEA TO ANY LAWS OR RULES	✓	
PHARMACY SHARES A REAL-TIME COMMON DATABASE WITH OTHER PHARMACIES	✓	
PHARMACY UTILIZE THE SERVICES OF A CENTRAL FILL PHARMACY		✓
VERIFYING PHARMACIST(S) IS DOCUMENTED	✓	
PHARMACY PERSONNEL WEAR APPROPRIATE NAME TAGS	✓	
PROCEDURE TO ENSURE ALL WHO WORK IN THE PHARMACY ARE APPROPRIATELY AND CURRENTLY REGISTERED OR LICENSED AND TRAINED TO PERFORM THEIR DUTIES	✓	
SIGN(S) POSTED REGARDING PHARMACY HOURS OF OPERATION	✓	
COMMENTS: Fedex primarily UPS some also couriers		

I have participated in an inspection and have reviewed the Inspection Report with the Investigator.

Print Name Bryan ONeill Signature [signature]

Title MOR License No. PH23692

Investigator Cheryl Latham Date 07/08/10

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
Board of Registration in Pharmacy
Investigative Report

In the Matters of:
1. **PHA-2010-0107** Ameridose, LLC, located on 50 Fountain Street in Framingham, MA (DS3467; Issued 07/13/06)

2. **PHA-2010-0108** Ameridose, LLC, located on 20 Flanders Road in Westborough, MA (DS89641; Issued 11/21/08)

Manger of Record:
1. Sophia Pasedis (PH20217; Issued 06/24/1987; no prior complaints)

2. Bryan M. O'Neill (PH23692; Issued 06/23/1997; no prior complaints)

Investigator: Cheryl Lathum, PharmD, RPh

Supervisor: Samuel J. Penta, RPh

Allegation of Complaint: give nature code and summarize the allegations:

The complainant (a specialty pharmaceutical company) alleges that Ameridose, LLC located on 50 Fountain Street in Framingham (DS3467; no prior complaints) and Ameridose, LLC located on 20 Flanders Road in Westborough (DS89641; no prior complaints) manufacture and distribute an unapproved, pre-mixed nicardipine injection product. The complainant further alleges that the manufacture of this product "is unavoidably dangerous under the conditions of its use and poses an immediate risk of death for critically ill patients to whom it is administered."

Nicardipine injection is a calcium channel blocker indicated for "the short-term treatment of hypertension when oral therapy is not feasible or not desirable."

There are two forms of nicardipine injection approved by the FDA. The first is nicardipine (2.5 mg/ml) in 10 ml glass ampoules, for dilution in 240 ml of intravenous fluid. It is available as Cardene IV from [redacted] Inc and from various generic manufacturers. The second is Cardene I.V. Premixed Injection. It is supplied as a single-use, ready-to-use, iso-osmotic solution for intravenous administration in a 200 mL Galaxy ® container with 40 mg (0.2 mg/mL) nicardipine hydrochloride in either dextrose or sodium chloride. The pre-mixed bags are manufactured by Baxter Healthcare Corporation and marketed by [redacted]

Ameridose manufacturers its pre-mixed nicardipine injection product by obtaining nicardipine ampoule products from hospital customers and by admixing the hospital's own nicardipine into commercially available diluent bags. Ameridose returns the finished products to hospitals, which store the bags until needed.

The complainant states that once diluted, nicardipine solution has a very short, 24-hour stability period at room temperature. The complainant further states, "Ameridose's practice of simply admixing nicardipine from approved ampoule products into an off-the-shelf I.V. bag cannot result in a ready-to-use nicardipine injection product that will be safe, pure, and stable beyond the 24 hour period specified in the FDA-approved labeling for ampoule products." The complainant continues, "The percent of nicardipine remaining in solution decreases as function of pH over a twenty-four hour period." The pH, concentration of the active ingredient, and the composition of the container material affect the stability of the active ingredient and the formation of impurities.

Activities and Findings:

On July 8, 2010 Board Investigators, with FDA Investigators, performed a site visit of both Ameridose's Framingham (DS3467; no prior complaints) and Westborough, Massachusetts (DS89641; no prior complaints) facilities. The MOR of the Framingham facility was identified as Sophia Pasedis (PH20217; Issued 06/24/1987; no prior complaints); the MOR of the Westborough facility was identified as Bryan M. O'Neill (PH23692; Issued 06/23/1997; no prior complaints).

At the time of the visit, the Framingham facility located on 50 Fountain Street in Framingham, MA was undergoing renovations with very limited operations and staff on site.

The Westborough facility, located on 20 Flanders Road in Westborough, was fully operational. An inspection was conducted of the facility's retail pharmacy license. No violation of Board of Pharmacy rules or regulations was found.

In a written response to [redacted] allegations dated July 15, 2010, Ameridose states, "Ameridose does not manufacture this product, but rather its pharmacists are admixing the hospital's own Nicardipine into a commercially available diluent bag just as the hospital pharmacist would but rather in a far more controlled and advanced cGMP environment." Ameridose also states that "multiple stability studies, completed by independent, FDA registered labs, which show that the admixed version(s) of Nicardipine admixed by Ameridose on behalf of its client hospitals, meet all stability, pH, sterility and other final admixed product requirements."

Ameridose further states that they have "hundreds of studies that address the sterility of its admixed medications" and that all admixing occurs "in ISO 5 environments inside state of the art clean rooms." Ameridose, continues, "Ameridose's operations exceed the requirements of USP <797> and meet cGMPs."

In a written, signed letter dated January 14, 2011, [redacted] stated that [redacted] and Ameridose, LLC ("Ameridose") have reached an amicable resolution to the companies' dispute regarding Ameridose's activities involving nicardipine."

The letter continues, "Accordingly, [redacted] no longer believes that any governmental investigative or enforcement actions against Ameridose are necessary to protect the public health

and safety and hereby withdraws its request that the Board of Registration in Pharmacy take any such actions."

Investigator Signature: _____ Date: 02/10/11

Supervisor Signature: _____ Date: 2/10/11

Addendum:

Investigator Penta spoke with FDA Investigator [redacted] on February 9, 2011. Per Investigator Emerson, at this time the FDA is not moving forward on this matter and the matter is administratively closed. If the matter is re-opened we will be contacted by FDA.

Wiley Rein LLP

1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

7925 JONES BRANCH DRIVE
McLEAN, VA 22102
PHONE 703.905.2800
FAX 703.905.2820

www.wileyrein.com

June 30, 2010

James N. Czaban
202.719.7411
jczaban@wileyrein.com

VIA E-MAIL AND OVERNIGHT DELIVERY

James D. Coffey, Director
Board of Registration in Pharmacy
239 Causeway Street, 2nd Floor, Suite 200
Boston, MA 02114

Re: **Complaint Against Ameridose LLC for Unlawful Manufacturing and Distribution of Pre-Mixed Nicardipine Injection Products**

Dear Mr. Coffey:

On behalf of [redacted] I am writing to call your attention to serious violations of Massachusetts pharmacy laws and regulations by Ameridose, LLC ("Ameridose"), of Framingham and Westborough, Massachusetts, and to request that prompt investigation and disciplinary actions be taken against Ameridose by the Board of Registration in Pharmacy (the "Board").

The unlawful actions of Ameridose involve the manufacturing and distribution of an unapproved injectable prescription drug product – specifically a pre-mixed nicardipine injection product – which is unavoidably dangerous under the conditions of its use and poses an immediate risk of death for critically ill patients to whom it is administered.

As indicated below, Ameridose is a Massachusetts-based company with two Massachusetts facilities, and holds six Massachusetts Pharmacy Licenses:

Ameridose, LLC
50 Fountain Street
Framingham, MA 01702
Phone: 888-820-0622
Phone: 508-656-2649
Fax: 508-872-0044

Mass. Pharmacy Licenses:
DS3467 (Retail Drug Store)
CS3467 (Controlled Substance)
CF3467 (Cert. of Fitness)

Ameridose, LLC
205 Flanders Road
Westborough, MA 01581
Phone: 888-820-0622
Phone: 508-656-2649
Fax: 508-872-0044

Mass. Pharmacy Licenses:
DS89641 (Retail Drug Store)
CS89641 (Controlled Substance)
CF89641 (Cert. of Fitness)

Thus the Board has jurisdiction, and the legal obligation, to investigate this matter and take appropriate disciplinary action to enforce the law and protect the public health.

I. BACKGROUND – NICARDIPINE INJECTION PRODUCTS

A. FDA-Approved Products

Nicardipine injection products are indicated for "the short-term treatment of hypertension when oral therapy is not feasible or not desirable." In practice, nicardipine injections are administered to hospitalized patients with elevated blood pressure due to serious medical events such a stroke, aortic dissections, elevated blood pressure due to kidney disease, or central nervous system (CNS) injury, where rapid reduction of blood pressure as a life-saving intervention is warranted.[1]

There are two forms of nicardipine injection approved by FDA pursuant to the federal Food, Drug, and Cosmetic Act ("FDCA"):

- Nicardipine (2.5 mg/mL) in 10 mL glass ampoules, for dilution in 240 mL of intravenous fluid; available from EKR as Cardene® I.V. (nicardipine for injection) and from various generic manufacturers. This form of nicardipine was first approved in 1992.

- Cardene® I.V. Pre-Mixed Injection 20 mg or 40 mg (0.1mg/mL or 0.2 mg/mL), in 200 mL Galaxy® bags ("Cardene® RTU"). For each strength of Cardene® RTU there are two diluent solution options: dextrose or sodium chloride. This product form was approved in 2008.

B. Ameridose's Unapproved Nicardipine Injection Product

Ameridose manufactures its pre-mixed nicardipine injection product by obtaining nicardipine ampoule products from hospital customers, diluting and filling the modified product into off-the-shelf I.V. bags, and returning the finished product to hospitals which store the bags until needed. The Ameridose product is not FDA-

[1] *See* P.E. Marik & J. Varon, 131 *CHEST* 1949–62 (2007); A.I. Qureshi, 118 *Circulation* 176–87 (2008); A.M. Pancioli, 51 *Ann. Emerg. Med.* S24-S27 (2008).

approved, and as discussed below, it is unavoidably dangerous under the conditions of its use, poses an immediate risk of death for patients to whom it is administered, is misbranded and deceptive, and is being unlawfully manufactured and distributed in violation of the FDCA and Massachusetts law.

II. AMERIDOSE'S PRE-FILLED NICARDIPINE INJECTION PRODUCT POSES SERIOUS SAFETY RISKS

A. Nicardipine Injection Ampoules Have Very Short Stability After Being Filled Into I.V. Bags

The major drawback of nicardipine ampoules is that the product requires dilution with 240 mL of a suitable intravenous fluid before being administered by slow infusion at a final concentration of 0.1 mg./mL. Importantly, once diluted, the nicardipine solution has a very short, 24-hour stability period at room temperature. As the FDA-approved labeling for Cardene® I.V. ampoules (and equivalent generic products) warns, "THE DILUTED SOLUTION IS STABLE FOR 24 HOURS AT ROOM TEMPERATURE" (capital letters in original). Thus, for both safety and efficacy reasons, hospitals must wait until they have an identified patient in need of the drug before diluting the drug and filling it into an I.V. bag for immediate administration. Ameridose's practice of simply admixing nicardipine from approved ampoule products into an off-the-shelf I.V. bag cannot result in a ready-to-use nicardipine injection product that will be safe, pure and stable beyond the 24 hour period specified in the FDA-approved labeling for the ampoule products.

B. Ameridose's Manufacturing Process Cannot Overcome the Short-Stability Problem

The short-stability problem of diluted nicardipine ampoules, as well as difficulties in producing a sterile pre-filled nicardipine I.V. bag, posed technical barriers to the development of a pre-mixed ready-to-use product. However, through extensive research and development efforts, [redacted] was able to develop Cardene® RTU as the first and only shelf-stable[2] and sterile pre-mixed ready-to-use nicardipine injection product. FDA approved Cardene® RTU in 2008. And, reflecting the novelty of Cardene® RTU, and the innovation required to develop and produce such a product,

[2] Unlike diluted solution created using nicardipine ampoules, the Cardene® I.V. Premixed solution has a stable room temperature shelf life of up to two years.

the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,612,102 (the '102 Patent) which covers pre-mixed ready-to-use nicardipine solution drug products.[3] The '102 patent describes the technical difficulties that must be addressed in order to product a safe and stable pre-mixed nicardipine product as follows:

> The production of stable, ready-to-use, premixed pharmaceutical compositions comprising nicardipine and/or its pharmaceutically acceptable salts as the active ingredient presents different development hurdles than does the development of the concentrated ampul product sold commercially as Cardene® RTM[4] I.V. As shown in FIG. 1, the percent of nicardipine remaining in solution decreases as function of pH over a twenty-four hour period. The percent decrease in nicardipine varies with the diluent and container chosen by the hospital staff.
>
> As described in the Examples, pH, the concentration of the active ingredient, and the composition of the container material affect the stability of the active ingredient and the formation of impurities. Thus, the development of a stable, ready-to-use premixed pharmaceutical composition requires simultaneous optimization of pH and nicardipine hydrochloride concentration, as well as selection of a pharmaceutically compatible container.

'102 Patent, § 5.2 (emphasis added).

[redacted] solved the stability and sterility problems for pre-mixed nicardipine products through a combination of a modified pH range and the use of specially-designed Galaxy® I.V. bags, filled using Baxter's proprietary "Seal/Fill/Seal" aseptic manufacturing process. In the Galaxy® Seal/Fill/Seal process a special PL 2501 plastic film is sterilized by passage through a hydrogen peroxide (H_2O_2) bath in the Galaxy® machine, and the bulk solution, film, and closure components are brought together and assembled within the interior of the Seal/Fill/Seal machine. Because

---

[3] A copy of the patent can be viewed at http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=7,612,102.PN.&OS=PN/7,612,102&RS=PN/7,612,102.

[4] Here, "RTM" stands for "Ready-to-Mix."

nicardipine is especially light-sensitive, the Galaxy® bag for the finished Cardene® RTU product uses an opaque outer film to protect the product from light-induced degradation. These processes and components for producing a shelf-stable and sterile pre-filled nicardipine product were extensively studied by [redacted] and the data and results were reviewed by the FDA in connection with the approval of [redacted] NDA for the Cardene® RTU product. *See* NDA 19-734/S-013 and S-014. No such FDA review has been conducted with respect to Ameridose's manufacturing processes and product components.[5]

Nicardipine ampoule products are sterile when manufactured, but that sterility is broken immediately upon opening the ampoule for dilution and filling into an I.V. bag. Where the diluted product is used immediately after being mixed, no sterility-related safety concerns would be expected. However, a pre-filled nicardipine I.V. bag that is not intended for immediate use could pose safety problems unless the entire contents and components of the product are appropriately sterilized.

[redacted] is unaware of what, if any, sterilization processes Ameridose uses for its pre-filled nicardipine product, but it is important to note that terminal sterilization techniques may not be safe and effective for such products. In its development work for the Cardene® RTU product, [redacted] studied the use of terminal sterilization with alternative I.V. bag systems but as [redacted] reported to FDA in its New Drug Application ("NDA") for Cardene® RTU, "[t]erminal sterilization . . . impacted nicardipine hydrochloride concentration and impurity levels to an extent that development of a commercially viable terminally sterilized nicardipine hydrochloride premixed product was not feasible." NDA No. 19-734/S-013, Module 2, Table P.2.2-2. The fact that Ameridose may be using sterilization techniques that have not been reviewed or approved by FDA and which may actually exacerbate the product's stability and impurity levels should be especially concerning to the Board.

C. Ameridose's False and Misleading Stability Claims

Ameridose cannot assure the safety of its pre-filled nicardipine I.V. bags. By filling its bags at a remote location and then shipping them to its hospital customers, it is

[5] It is notable that Ameridose has had manufacturing problems in the recent past, specifically, a 2008 recall of pre-fliled fentanyl I.V. bags due to super-potency. *See* FDA Enforcement Report at www.fda.gov/Safety/Recalls/EnforcementReports/2008/ucm120532.htm.

inevitable that most if not all of Ameridose's products will be used in patients far longer than 24 hours after being filled, and thus will be beyond the documented stability period for diluted nicardipine ampoules. Yet despite the serious life-threatening risk to patients posed by degraded nicardipine injection products, Ameridose's business model reflects its intent that its products be stored in hospital inventories for weeks before use. This intended use is further evidenced by the fact that, to [redacted]nderstanding, Ameridose represents, through altered and unapproved labeling, and/or oral representations by Ameridose sales agents, that its pre-mixed nicardipine products has 75 days of shelf-life stability. This claim is directly contrary to the stability warning and instructions in the approved labeling for nicardipine ampoule products that Ameridose uses to create its pre-mixed product, and EKR is not aware of any scientifically sound bases to support extended stability dating for Ameridose's pre-mixed product.

II. THE AMERIDOSE PRODUCT IS UNLAWFUL UNDER MASSACHUSETTS LAW

Ameridose's manufacturing and distribution of its pre-mixed nicardipine injection product violates Massachusetts law and the Board's regulations, specifically, the Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments (the "Code of Conduct"), 247 Code of Massachusetts Regulations § 9.01, law in several ways.

A. Nonconformity With Federal Law in Violation of § 9.01(1).

The Code of Conduct, § 9.01(1), requires that "a registered pharmacist shall at all times conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board." Ameridose is in violation of § 9.01(1) because its pre-mixed nicardipine injection product violates federal law. Specifically, the Ameridose product is a "new drug"[6] and because it is not the subject of an approved New Drug Application, the product violates the FDCA. *See* 21 U.S.C. §§ 355(a) (requiring FDA approval of all "new drugs"), 331(d) (prohibiting distribution of an unapproved new drug in violation of § 355). Moreover, the fact that Ameridose modifies FDA-approved nicardipine ampoules violates FDA regulations which require prior FDA approval for the types

[6] *See* 21 U.S.C. §§ 321(p) (defining "new drug"); *see also Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 619, 629-30 (1973) (explaining the definition of "new drug").

of changes Ameridose makes in converting nicardipine ampoules into pre-filled I.V. bags. *See* 21 C.F.R. § 314.70(b).[7]

B. Dispensing a Drug in a Manner Intended To Circumvent Law in Violation of § 9.01(2).

The Code of Conduct, § 9.01(2), also prohibits a pharmacist from dispensing a drug "in a manner which is intended, either directly or indirectly, to circumvent the law." By modifying nicardipine ampoules into pre-mixed I.V. bags without FDA approval, Ameridose is, directly or indirectly, circumventing the very FDA regulations that EKR followed in order to obtain approval of its NDA, and thus violates § 9.01(2).

Moreover, Ameridose's product is essentially an attempted (and unapproved) copy of a commercially available product – Cardene® RTU – that FDA has carefully reviewed and approved for safety and efficacy. As FDA itself has stated, this type of activity "circumvents important public health requirements and undermines the drug approval process – the evidence-based system of drug review that consumers and health professionals rely on for safe and effective drugs."[8]

In addition, any representation by Ameridose that its product is a "pharmacy compounded" product exempt from FDA regulation would be false and would also reflect an intent to circumvent the requirements of federal law. FDA has long recognized the deceptive and evasive intent of some companies claiming to be

---

[7] Under this regulation, prior FDA approval is required for "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities," including,

- "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients. . . ."
- "changes that may affect drug substance or drug product sterility assurance. . . ."
- "changes in a drug product container closure system that controls the drug product delivered to the patient or changes in the type. . . (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe) . . . of a packaging component that may affect the impurity profile of the drug product. . . ."

[8] Statement of Steven K. Galson, CDER, "Federal and State Role in Pharmacy Compounding and Reconstitution: Exploring the Right Mix to Protect Patients," before the S. Comm. on Health, Ed., Labor, and Pensions (Oct. 23, 2003) (emphasis added).

"compounding pharmacies," as described in the agency's Compliance Policy Guidance on Pharmacy Compounding (the "Compounding CPG"):

> Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies.
>
> * * *
>
> [W]hen the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action.[9]

C. **Deceptive Acts in Violation of § 9.01(6)**

The Code of Conduct, § 9.01(6), requires that "[a] pharmacist shall not engage in any fraudulent or deceptive act." Ameridose is committing deceptive acts in violation of § 9.01(6) because, to [redacted] understanding, Ameridose represents, through new labeling, sales representative statements, or otherwise, that the product is stable for 75 days from the date of its manufacture when in fact, according to FDA, a diluted nicardipine ampoule product is not stable beyond 24 hours. Ameridose's representations regarding extended stability of its product are therefore deceptive in violation of Code of Conduct § 9.01(1), and also render the product misbranded in violation of the FDCA, which provides that a drug product is misbranded "[i]f its labeling is false or misleading in any particular," or if "it is dangerous to health when used in the dosage or manner...suggested in the labeling thereof." 21 U.S.C. §§ 352(a), 352(j).

[9] FDA Compliance Policy Guide Manual, § 460.200 (2002).

D. Distributing Expired, Outdated and Substandard Drugs in Violation of § 9.01(10)

The Code of Conduct, § 9.01(10), also generally prohibits pharmacists from "dispens[ing] or distribut[ing] expired, outdated or otherwise substandard drugs. . . ." As described above, Ameridose's pre-mixed nicardipine injection product expires and becomes outdated a mere 24 hours after it is mixed, yet as distributed by Ameridose and used by hospitals, the product is not used in patients until days or weeks after it has expired. Thus, Ameridose is also violating Code of Conduct section 9.01(1) by its manufacturing and distribution of its pre-mixed nicardipine injection product.

III. THE BOARD CAN AND SHOULD TAKE PROMPT DISCIPLINARY ACTION AGAINST AMERIDOSE

Under the Code of Massachusetts Regulations, 247 CMR 10.03(1), "the Board may impose disciplinary action against an individual or entity licensed or registered by the Board" for violations of the pharmacy laws or regulations, or on one or more other grounds, including:

> "(k) Engaging in conduct that has the capacity or potential to place the public health, safety or welfare at risk;" and
>
> "(*l*) Engaging in conduct that has the capacity or potential to deceive or defraud."

247 CMR § 10.03(k) & (*l*).

Both of these bases for disciplinary action apply in this case. As described above, Ameridose's pre-mixed nicardipine injection product is unsafe, and puts the public health at risk, because its extremely short stability period means that patients who receive the drug will be receiving an expired, outdated, and substandard product. Moreover, because Ameridose represents that its product is safe and stable for much longer than 24 hours after being filled, when in fact the FDA has determined that the product is stable for no more than 24 hours, Ameridose's activities are deceptive.

CONCLUSION

Ameridose's unapproved pre-filled nicardipine I.V. product is unsafe and unlawful, and the Board should take immediate action to prevent further distribution of this product.

Please contact the undersigned if you have any questions or require additional information.

Respectfully submitted,

Jim Czaban/NC

James N. Czaban

Nathan S. Carden

[redacted]

cc: [redacted]

Wiley Rein LLP

1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

7925 JONES BRANCH DRIVE
McLEAN, VA 22102
PHONE 703.905.2800
FAX 703.905.2820

www.wileyrein.com

January 14, 2011

James N. Czaban
202.719.7411
jczaban@wileyrein.com

VIA UPS

James D. Coffey, Director
Board of Registration in Pharmacy
239 Causeway Street, 2nd Floor, Suite 200
Boston, MA 02114

Contains Confidential Commercial Information and Trade Secrets; Exempt From Public Disclosure Pursuant to Massachusetts Public Records Law, G. L. c. 4, § 7(26)(g)

Re: Pre-Mixed Nicardipine Injection – Notice of Settlement Between [redacted] and Ameridose LLC

Dear Mr. Coffey:

On behalf of [redacted], and further to our prior correspondence, I am writing to inform you that [redacted] and Ameridose LLC ("Ameridose") have reached an amicable resolution to the companies' dispute regarding Ameridose's activities involving nicardipine.

Accordingly, [redacted] no longer believes that any governmental investigative or enforcement actions against Ameridose are necessary to protect the public health and safety and hereby withdraws its request that the Board of Registration in Pharmacy take any such actions.

We appreciate your attention to this matter.

Respectfully submitted,

James N. Czaban
Counsel to [redacted]

cc: [redacted]